Research Article

EVIDENCE FOR SUCCESSFUL IMPLEMENTATION OF EXPOSURE AND RESPONSE PREVENTION IN A NATURALISTIC GROUP FORMAT FOR PEDIATRIC OCD

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> Background: Although exposure and response prevention (ERP) is an effective treatment for youth with obsessive-compulsive disorder (OCD), the majority of studies, randomized clinical trials of individual therapy, find variability in treatment response. We evaluated the potential role of individual differences in OCD presentation, comorbid disorders, age, and gender on treatment effects. Moreover, we examined these potential effects in a group format in a naturalistic, clinic-based sample of patients. Methods: Pediatric patients with a DSM-IV diagnosis of OCD (n = 41) were treated with ERP in an intensive outpatient community-based program. OCD, mood, and anxiety symptom severity was measured at baseline, during treatment, and at discharge. Trajectories and predictors of treatment outcome were measured using linear growth models. Results: We found that group-based ERP was effective in reducing pediatric OCD symptom severity in a naturalistic treatment setting irrespective of age or gender. Furthermore, ERP was found to be effective at reducing depressive symptoms but not other anxiety symptoms. We also found inter-individual variability in the discharge levels of contamination, symmetry, and intrusive sexual thoughts and in the rate of severity reduction of intrusive sexual thoughts. Conclusion: Group-based ERP is an effective treatment for children and adolescents with OCD. Several factors, including symptom dimensions and comorbid psychopathology, are associated with treatment response and outcome in this pediatric population. Depression and Anxiety 28:342-348, 2011. © 2011 Wiley-Liss, Inc.

Key words: OCD; treatment; naturalistic study

INTRODUCTION

Although exposure and response prevention (ERP) is now considered the first-line treatment for pediatric obsessive–compulsive disorder (OCD),^[1–4] questions remain regarding the efficacy of this treatment approach in nonresearch contexts and how individual factors influence treatment response. While cognitive behavior therapy, specifically ERP,^[5] is an effective

³Department of Psychiatry, Mount Sinai School of Medicine, New York, New York The authors discose the following financial relationships within the past 3 years: Contract grant sponsor: NIH and National Center for Resarch Resources; Contract grant numbers: T32MH018951; KL2RR024154.

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Dr. Birmaher is a consultant for Schering Plough; serves on the Major Depressive Disorder Regional Advisory Board for Dey Pharma, L.P.; and has and will receive royalties from Random House, Inc., and Lippincott Williams & Wilkins. No other authors report any conflicts.

Received for publication 21 September 2010; Revised 8 December 2010; Accepted 22 December 2010

DOI 10.1002/da.20789

Published online 24 February 2011 in Wiley Online Library (wiley onlinelibrary.com).

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treatment for children and adolescents with OCD, a large minority of youth continue to experience moderate to high levels of symptoms and/or cooccurring behavioral and emotional problems following treatment (e.g.^[5–8]). Additional investigations are needed to elucidate the potential role of individual differences in OCD-presentation, co-morbid internalizing and externalizing disorders, and age on treatment response.^[1] Because the majority of the literature has been informed by randomized clinical trials (RCTs),^[1,5,8–10] findings from community-based treatment programs might contribute important information for treatment planning across multiple settings.

Reviews and meta-analyses have consistently concluded that ERP administered either alone or in conjunction with medication is more efficient at reducing overall OCD symptom severity than medication alone.^[2,3] These studies focused on results of RCT, which are necessary to build an empirical basis for treatment recommendations. However, concerns are often raised about the generalizability of findings from RCTs due to excluding many individuals seen in standard practice. Thus, naturalistic clinic-based samples are needed to examine the generalizability of conclusions from research settings.

Although primary studies find that ERP for OCD is an effective treatment, these studies find variability in treatment response^[2,3] and it is important to understand this variation. One possibility is that treatment response is typically assessed based on total OCD severity, which includes multiple symptom dimensions (e.g., intrusive thoughts, contamination)^[2,3] that are not present in all individuals. Thus, specific dimension scores may be used to examine specificity of treatment response.

A second possibility is that heterogeneity in treatment response to ERP may be partially explained by joint pharmacotherapy. Some suggest that ERP and pharmacotherapy may target different features of the disorder^[11] or dimensions of symptomatology.^[12–14] Again, few studies measure the effects of treatment modalities on separate dimensions of OCD.^[8]

In addition to dimensions of OCD presentation, demographic and clinical characteristics may also influence treatment outcome. Developmental level and sex are particularly intertwined in the context of OCD.^[14] Age of onset of OCD is bimodal with childhood onset seen primarily in boys, whereas later adolescent or adult onset OCD is more common in girls.^[6,15] Thus, examinations of differential treatment response by age and sex may provide information about specificity of (non) response. One meta-analysis did not find that age or sex was associated with treatment outcome in research settings;^[16] however, it remains unknown whether this is found in uncontrolled settings as well.

Comorbidity is also particularly important to consider as a predictor of treatment outcome. Externalizing problems, especially attention deficit/hyperactivity disorder (ADHD), commonly co-occur with pediatric OCD.^[6,17] Recent reviews have suggested that oppositional-defiant disorder and conduct disorder are both associated with poorer response to treatment for OCD.^[11,16,17] However, these reviews reached conflicting conclusions with regard for the role of ADHD and treatment response.^[11,16]

Internalizing disorders may also influence OC treatment response. Co-morbid anxiety disorders may represent greater severity and require additional interventions beyond ERP to produce clinically significant changes. Additionally, co-morbid depressive disorders may serve as a barrier to treatment engagement and reduce the efficacy of ERP. Conversely, the impact of ERP on co-occurring symptoms of internalizing disorders is relatively under explored. Examination of whether ERP influences symptoms beyond OCD is important in developing and managing treatment plans. Despite these possibilities, the current body of work finds few robust associations between comorbid anxiety and/or depressive disorders and OCD treatment outcome.^[8,16,17]

Finally, because group-based services can provide a more cost-effective medium of therapy than that of one-on-one treatment, investigation of the efficacy of ERP in a group format is of importance. There is some evidence to suggest that providing ERP in a group format is a viable vehicle of treatment provision; however, these data come from a controlled research setting.^[9] Thus, it remains unknown whether this treatment approach provides similar effectiveness in naturalistic treatment settings.

This study seeks to examine OCD treatment response in a naturalistic clinic-based sample using total OCD severity and multiple specific dimensions of OCD symptomatology. We also examine differences in treatment response as a function of demographic and clinical characteristics, including history of pharmacotherapy.

METHODS

PARTICIPANTS

Participants were patients who consented to be part of a research registry as part of their treatment at the Pediatric Obsessive–Compulsive Disorder Intensive Outpatient Program (OCD-IOP). Between October 2005 and December 2008, 41 patients consented to being part of the research registry and were included in this study. The average age of the participants was 12.36 years (SD = 2.76 years; ranging from 6 to 17 years) and 22 (53%) were female. Patients were enrolled in treatment for an average of 12.13 weeks (SD = 6.58 weeks).

The pediatric OCD-IOP involves multiple treatment modalities. Patients participate in up to four group sessions per week, each of which lasts 2 hr and 15 min. These group sessions are led by two masters-level clinicians and utilize ERP, following the *Up and Down the Worry Hill* protocol.^[18] This treatment protocol outlines assessment, treatment readiness, development of individualized exposure hierarchies, and principles of implementing ERP with youth and their families. Family members participate in bi-weekly individualized therapy sessions that focus on psychoeducation and a

weekly parent support group focusing on psychoeducation and coping with children with OCD. Patients are seen by a child psychiatrist weekly to be evaluated for appropriateness for, need of, and alterations in medication. Most (n = 36 [87.8%]) of the patients seen in the clinic had a history of psychotropic medication use. However, the registry did not characterize specific medications, dosages, and length of use.

MEASURES

The Children's Yale–Brown Obsessive–Compulsive Scale (CY-BOCS) is a downward extension of the Yale–Brown Obsessive–Compulsive Scale. The CY-BOCS is a 10-item, clinician-rated, semi-structured instrument used to assess OCD severity over the past week. The scale provides indices of obsessions, compulsions, and an overall total score. Previous work finds that the scales demonstrate good psychometric properties, including internal consistency, inter-rater reliability, and convergent and divergent validity.^[19]

The Dimensional Yale-Brown Obsessive Compulsive Scale (DY-BOCS) is another downward extension of the Yale-Brown Obsessive-Compulsive Scale. The DY-BOCS is an 88-item selfreport checklist that is scored using clinician-rated, semi-structured criteria.^[20] The scale provides severity of symptoms related to obsessions of harm due to aggression/injury/violence/natural disasters and related compulsions; obsessions concerning sexual/ moral/religious obsessions and related compulsions: obsessions about symmetry/"just-right" perceptions, and compulsions to count or order/arrange; contamination obsessions and cleaning compulsions; obsessions and compulsions related to hoarding and miscellaneous obsessions and compulsions that relate to somatic concerns and superstitions, among other symptoms. In addition to these sub-scales, the DY-BOCS provides a total symptom severity score. Previous work finds that the scales demonstrate good psychometric properties, including internal consistency, inter-rater reliability, and convergent and divergent validity.

The Screen for Anxiety and Related Disorders (SCARED) is a 41-item self-report measure that assesses symptoms of somatic anxiety/panic; general anxiety; separation anxiety; social phobia; and school phobia. Previous work finds that the scales demonstrate good psychometric properties, including internal consistency, parent–child agreement, and convergent and divergent validity.^[21]

The Moods and Feelings Questionnaire (MFQ) is a 33-item selfreport measure of depressive symptomatology.^[22,23] Previous work finds that the scales demonstrate good psychometric properties, including internal consistency, parent–child agreement, and convergent and divergent validity.

Patients completed symptom severity measures at intake, approximately 6 weeks into treatment (M = 5.71 weeks, SD = .81), and at discharge.

ADDITIONAL FACTORS

Medical records were examined to provide information on medication use before or during participation in the OCD-IOP. Patient records were also examined to identify lifetime history of comorbid depressive, anxiety, and ADHD.

DATA ANALYSIS

Trajectories of treatment outcome measures were modeled using Mplus 5.21^[24] using the TWOLEVEL and RANDOM analysis options. The MLM framework was used to estimate linear growth models. Unconditional growth models estimate trajectories using two primary parameters, intercept and slope, each of which have mean and variance estimates based on the relationship between time (here, defined as number of weeks enrolled in the OCD-IOP treatment) and

the symptom scores. The intercept is the estimated level of the outcome variable at an identified location of the growth pattern, in these analyses, at discharge. The intercept parameter is characterized by a variance estimate that identifies whether there is significant variation in levels of the outcome variable at the specified time value. The mean value of the slope is the estimated average rate of change over time in the observed data. The slope parameter is also characterized by a variance estimate that identifies whether there is significant variation in the rate of change in levels of the outcome variable. Thus, this modeling approach examines cross-sectional variability in the outcome for the slope. We examine predictors of intercept and/or slope only when those parameters have significant inter-individual variance.^[25]

RESULTS

Table 1 displays descriptive information about the sample. Overall, patients presented with moderate-severe OCD, as indexed by the observed mean for the CY-BOCS and DY-BOCS.

TRAJECTORIES OF OCD SYMPTOM SEVERITY

Trajectories of symptoms were estimated using growth models with individual symptom measure scores as level-one outcomes. Linear growth curves were estimated for each symptom measure separately with time in treatment as the predictor variable.

The unconditional growth model (see Table 2 for numeric results) for CY-BOCS Total Score showed that the mean CY-BOCS Total Score at discharge was significantly greater than 0; however, there was no significant variance in CY-BOCS Total Score at discharge. CY-BOCS Total Score decreased over the course of treatment; however, there was no significant

TABLE 1. Clinical characteristics of patients

Symptom dimension	M (SD)	n (%)	
OCD symptomatology			
CY-BOCS			
Obsessions	9.46 (5.22)		
Compulsions	9.96 (5.25)		
Total Score	19.42 (9.41)		
DY-BOCS			
Contamination	4.07 (4.49)		
Hoarding	1.19 (2.85)		
Symmetry	4.78 (4.35)		
Intrusive Thoughts: Harm	3.55 (4.63)		
Intrusive Thoughts: Sex	2.22 (3.68)		
Total score	17.62 (8.01)		
Comorbid symptomatology			
SCARED	16.52 (10.94)		
MFQ	12.86 (12.20)		
Comorbid disorders			
Anxiety D/O		5 (12.2)	
Depressive D/O		6 (14.6)	
ADHD		10 (24.4)	
Psychotropic medication use		36 (87.8)	

	Discharge s	ymptom level	Rate of symptom change	
Outcome measure	Mean	Variance	Mean	Variance
CY-BOCS				
Obsessions	5.72 (0.75)***	2.66 (4.03)	$45(.11)^{***}$.02 (.05)
Compulsions	5.69 (0.23)***	4.54 (7.85)	54 (.07)***	.00 (8.56)
Total score	11.39 (1.33)***	10.00 (13.40)	99 (.13)***	.01 (.26)
DY-BOCS				· · /
Contamination	2.84 (0.75)***	8.14 (3.72)*	13 (.13)	.01 (.05)
Hoarding	.58 (0.38)	2.19 (1.85)	09(.08)	.08 (.06)
Symmetry	3.23 (0.85)***	$5.48(3.25)^+$	$20(.09)^{*}$.01 (.06)
Intrusive Thoughts: Harm	$1.11(0.51)^*$	2.07 (2.19)	28 (.11)**	.14 (.06)*
Intrusive Thoughts: Sex	1.67 (0.64)**	6.54 (3.12)*	14 (.11)	.08 (.07)
Total score	11.74 (1.33)***	13.59 (10.61)	61 (.18)**	.07 (.11)
SCARED	15.48 (2.65)***	108.24 (31.56)**	21 (.29)	.25 (.35)
MFQ	9.88 (1.47)***	45.97 (15.12)**	31 (.17)+	.30 (.11)**

TABLE 2. Unconditional linear growth model results for all symptom outcomes

P*<.05; *P*<.01; ****P*<.001.

variance in the association between time in treatment and CY-BOCS Total Score. Similar patterns were found for CY-BOCS Obsession and Compulsion Scores with discharge symptoms being greater than 0 and symptoms reducing over the course of treatment. However, variance estimates for discharge symptoms and rate of symptom change were nonsignificant.

The unconditional growth model for DY-BOCS Total Score showed that the mean DY-BOCS Total Score at discharge was significantly greater than 0; however, there was no significant variance in DY-BOCS Total Score at discharge. DY-BOCS Total Score decreased over the course of treatment; however, there was no significant variance in the association between time in treatment and DY-BOCS Total Score. Specific dimensions of symptomatology demonstrated different patterns of results.

The unconditional growth model for DY-BOCS Contamination Score showed that the mean DY-BOCS Contamination Score at discharge was significantly greater than 0 and there was significant variance in DY-BOCS Contamination Score at discharge. DY-BOCS Contamination Score did not significantly decrease over the course of treatment and there was no significant variance in the association between time in treatment and DY-BOCS Contamination Score. The unconditional growth model for DY-BOCS Hoarding Score showed that the mean DY-BOCS Hoarding Score at discharge did not significantly differ from $\overline{0}$ and there was no significant variance in DY-BOCS Hoarding Score at discharge. DY-BOCS Hoarding Score did not significantly decrease over the course of treatment and there was no significant variance in the association between time in treatment and DY-BOCS Hoarding Score. The unconditional growth model for DY-BOCS Symmetry Score showed that the mean DY-BOCS Symmetry Score at discharge was significantly greater than 0 and there was significant variance in DY-BOCS Symmetry Score at discharge (at the level of a trend). DY-BOCS Symmetry Score significantly decreased over the course of treatment; however, there was no significant variance in the association between time in treatment and DY-BOCS Symmetry Score. The unconditional growth model for DY-BOCS Intrusive Thoughts of Harm Score showed that the mean DY-BOCS Intrusive Thoughts of Harm Score at discharge was significantly greater than 0; however, there was no significant variance in DY-BOCS Thoughts of Harm Score at discharge. DY-BOCS Intrusive Thoughts of Harm Score significantly decreased over the course of treatment and there was significant variance in the association between time in treatment and DY-BOCS Intrusive Thoughts of Harm Score. The unconditional growth model for DY-BOCS Intrusive Sexual Thoughts Score showed that the mean DY-BOCS Intrusive Sexual Thoughts Score at discharge was significantly greater than 0 and there was significant variance in DY-BOCS Intrusive Sexual Thoughts Score at discharge. DY-BOCS Intrusive Sexual Thoughts Score did not significantly decrease over the course of treatment and there was no significant variance in the association between time in treatment and DY-BOCS Intrusive Sexual Thoughts Score.

TRAJECTORIES OF DEPRESSIVE AND ANXIETY SYMPTOM SEVERITY

The unconditional growth model for SCARED Total Score showed that the mean SCARED Total Score at discharge was significantly greater than 0 and there was significant variance in SCARED Total Score at discharge. SCARED Total Score did not significantly decrease over the course of treatment and there was no significant variance in the association between time in treatment and MFQ Total Score.

The unconditional growth model for MFQ Total Score showed that the mean MFQ Total Score at

	DY-BOCS						
	Contam. (I)	Symmetry (I)	Int: Harm (S)	Int: Sex (I)	MFQ (I)	MFQ (S)	SCARED (I)
Age	0.27 (0.21)	04 (0.39)	.00 (.04)	0.20 (0.16)	0.13 (0.51)	08 (.06)	0.73 (0.75)
Sex	-0.84(1.45)	72 (1.46)	21 (.20)	1.11 (1.09)	0.72 (3.01)	.33 (.42)	1.92 (4.76)
Medication	3.24 (0.92)***	15 (1.41)	07 (.30)	0.20 (1.28)	9.51 (1.93)***	.65 (.19)**	9.79 (3.85)*
Anxiety D/O	-0.13(2.70)	-1.81(1.46)	.48 (.15)**	$-2.10(0.67)^{**}$	-8.79 (2.18)***	.08 (.22)	-9.37 (6.15)
Depressive D/O	$3.42(2.02)^+$.09 (1.93)	60 (.16)***	1.85 (1.91)	3.99 (3.68)	30 (.32)	6.70 (9.23)
ADHD	-2.19 (1.13)+	$-1.05(0.62)^+$.17 (.19)	-0.05 (1.22)	1.22 (2.47)	.62 (.26)*	-6.73 (4.89)

 TABLE 3. Predictors of treatment outcomes

Note: (I) indicates that the association with the intercept parameter (i.e., symptom level at discharge) is being estimated; (S) indicates that the association with the slope parameter (i.e., rate of symptom reduction) is being estimated. *P < .05; **P < .01; ***P < .001.

discharge was significantly greater than 0 and there was significant variance in MFQ Total Score at discharge. MFQ Total Score significantly decreased over the course of treatment (at the level of a trend) and there was significant variance in the association between time in treatment and MFQ Total Score.

PREDICTORS OF TREATMENT OUTCOME

We examined the associations between model parameters that had significant variance and a number of demographic (e.g., age, sex) and clinical (e.g., medication use; comorbid psychopathology) factors that may be associated with treatment outcome. Models examined the associations between OCD, depression, and anxiety severity and predictors individually. Outcomes were only considered when either (or both) the discharge level or rate of change of symptoms had significant variance.^[25]

Higher DY-BOCS Contamination Score at discharge was associated with medication use and comorbid depressive disorder (at the level of a trend) (Table 3). Lower DY-BOCS Contamination and Symmetry Scores (at the level of a trend) at discharge were associated with comorbid ADHD. Lower DY-BOCS Intrusive Sexual Thoughts Score at discharge was associated with comorbid anxiety disorder. Slower rates of reduction in DY-BOCS Intrusive Thoughts of Harm were associated with comorbid anxiety disorder. Faster rates of reduction in DY-BOCS Intrusive Thoughts of Harm were associated with comorbid depressive disorder.

Higher SCARED Scores at discharge were associated with medication use. Higher MFQ Scores at discharge were associated with medication use and lower MFQ scores were associated with comorbid anxiety disorder. Slower rates of MFQ scores were associated with comorbid ADHD.

DISCUSSION

Building on work from clinical trials of ERP for pediatric OCD, this study examined ERP for pediatric OCD in a naturalistic group treatment setting. Further, we examined multiple measures of symptoms, including specific dimensions of OCD and general anxiety and depressive symptomatology. Lastly, we examined factors that may influence treatment response, including demographic and clinical characteristics.

We found that the level of symptoms at discharge and rate of change in overall OCD symptom severity were similar for all patients. Interestingly, the amount of reduction in symptoms for this study was comparable to that from POTS,^[1] suggesting similar acute effects of ERP administered in a group and individual psychotherapy. However, the total symptom scores obscured findings for discharge level of symptoms and rate of change of symptoms within specific symptom dimensions. In particular, there was inter-individual variability in discharge levels of contamination, symmetry, and intrusive sexual thoughts and inter-individual variability in rate of reduction of intrusive sexual thoughts. These results suggest that further treatment development may benefit from considering specific symptom dimensions.^[13]

In addition to our focus on multiple dimensions of OCD symptoms, we also investigated non-OCD anxiety symptoms and depressive symptoms. Our analyses revealed that ERP treatment was associated with reduction in depressive symptoms, but not other anxiety symptoms. These data suggest that ERP has an impact on depressive symptoms, at the level of a threshold disorder or considering sub-syndromal symptoms, even when they are not an explicit focus of the treatment. Our null findings for non-OCD anxiety symptoms may highlight that the ERP hierarchy focused on OCD specific symptoms and behaviors and other intervention strategies may be needed to address other forms of anxiety within this population.

Our results concerning the relationship between history of medication use and termination levels of OCD, non-OCD anxiety, and depressive symptoms may appear surprising. These results suggest that those youth who do not have a history of pharmacotheraypy have lower levels of symptoms and faster reduction of symptoms. One plausible explanation is that medication use is encouraged for those youth with marked OCD symptoms or comorbid disorders that reduce the efficacy of the ERP treatment.

We found that levels of contamination and symmetry obsessions, intrusive sexual thoughts, and non-OCD anxiety and depressive symptomatology at termination were not associated with age or sex. These null findings suggest that the interventions work equally well across the age range of the clinic population (i.e., age 6 through 17) and for both genders. Similar to one previous review,^[16] these findings suggest that this form of intervention is developmentally robust and expectations for treatment gains are expected to be equivalent for boys and girls.

Comorbid psychopathology was also investigated as a potential explanatory variable for heterogeneity in treatment response. Contrary to past work, [6,11,16,17] we found that comorbid ADHD was associated with lower levels of contamination and symmetry obsessions upon treatment termination (at the level of a trend). This finding was surprising as ERP relies on patients to focus on anxiety provoking stimuli for extended periods of time, which may be particularly difficult for individuals with attention problems. However, youth with comorbid ADHD may have developed alternative strategies to allocate attention through other behavioral interventions or pharmacological agents that facilitates their participation in ERP. This is plausible as all youth with comorbid ADHD had a history of medication use. Similarly, we found that comorbid anxiety disorder was associated with lower levels of intrusive sexual thoughts and depressive symptoms at the end of treatment. These data suggest that, for youth with additional anxiety disorders, improvement in their OCD-related symptoms is associated with a reduction in mood symptoms.

In addition to examining final symptom levels, we also examined associations between demographic and clinical characteristics and rate of symptom reduction. We found that rate of symptom reduction was not associated with age or gender, suggesting that youth will make treatment gains at similar rates. Comorbid depressive disorder was associated with a faster reduction in intrusive thoughts of harm. Some presentation of intrusive thoughts of harm may appear similar to passive death wish or other forms of suicidal ideation, which are similar to those seen in depressive disorder. Thus, more focused attention on these types of intrusive thoughts in depressed patients may result in faster symptom reduction in this domain. Although the past literature suggests that comorbidity is largely associated with poor outcomes,^[16,17] these data suggest greater heterogeneity in these relationships.

This study had a number of strengths, including repeated assessments of multiple dimensions of OCD symptomatolgy, non-OCD anxiety, and depression; consideration of demographic and clinical characteristics of patients as moderators of treatment response; and using a sophisticated modeling approach to assess treatment response.

However, the study also included a number of limitations. First, we did not focus on the role of medication in this study. Some suggest that ERP and pharmacotherapy may target different features of the disorder^[11] or dimensions of symptomatology.^[12–14] The research registry only considered whether the patient had a lifetime history of medication use through their participation in the intervention in a naturalistic setting. This gross-level data precluded fine-grained analyses considering onset of medication use, changes in doses, and classes of prescribed medication, which are essential to consider in the future. Similarly, patients were enrolled in the treatment program at differing levels (i.e., tapering out of the program; unequal attendance of family sessions). Thus, estimates do not reflect this variability. Finegrained analyses concerning this variability will also be important to consider in the future. Future naturalistic treatment studies should consider the use of propensity score analyses^[26] to account for differences in nonrandom selection for medication use and variability in treatment participation.

Second, the sample size was small. Although this should not significantly bias the results concerning the magnitude of symptom reduction, there were relatively few patients with specific comorbid disorders. Thus, estimates of associations between may be liberal.

Third, diagnoses of child psychopathology were based on routine clinical care, rather than structured interviews. Thus, diagnostic information may be less precise than in structured research settings.^[27] However, this limitation may increase the generalizability of the findings to diagnostic impressions in routine clinical practice.

Overall, this study finds evidence for the utility of ERP administered in a group format. Importantly, we found that treatment gains are similar across youth development and gender. However, our work demonstrated that it is important to consider specific dimensions of symptoms in examining the role of other factors as moderators of treatment response. We identified a number of patterns of associations between comorbid psychopathology and treatment outcome, suggesting that treatment modifications may be needed to better implement the intervention.

Acknowledgments. Dr. Olino was supported by T32MH018951. Dr. Gilbert was supported by KL2RR024154. Portions of this work were presented at the 2009 Meeting of the Anxiety Disorders Association of America.

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